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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,718	05/15/2007	Ernst V. Arnold	065611-0119	1962
22428	7590	07/07/2008	EXAMINER	
FOLEY AND LARDNER LLP			SUTTON, DARRYL C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,718	Applicant(s) ARNOLD ET AL.	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 5,8-12,14-17,19-27,29-36,38-48,50 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-4,6,7,13,18,28,37,49 and 51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>0/08/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's election with traverse of the Restriction requirement and species election in the reply filed on 02/21/2008 is acknowledged. The traversal is on the ground(s) that the Groups of the Restriction requirement all share a common structural feature, common utility, and can be searched without undue burden upon the Examiner. This is not found persuasive because the Groups of the Restriction requirement were formulated based on the difference in structure between a polymer that incorporates a phenyl group within the polymer backbone and a polymer that has a phenyl group that is pendant from the polymer backbone. These are two separate forms of a polymer and there is no common structural feature between the two. Lack of Unity of invention is the only requirement necessary for restriction of 371 applications, burden to the examiner is not considered; furthermore, burden to the examiner cannot be assessed until actual examination of the application takes place.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of Group IV and species of (a) phenyl group pendant to polymer, (c) R^2 =sodium, (d) polystyrene polymer, (g) phenyl group para to the polymer and corresponding claims 1-4, 6, 7, 13, 18, 28, 37, 49 and 51 in the reply filed on 10/22/2007 is acknowledged. Claims 5, 8-12, 14-17, 19-27, 29-36, 38-48, 50 and 52 are withdrawn from further consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 7, 13, 18, 28, 37, 49 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, courts have indicated what does not constitute same. See, e.g., In re Gostelli, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two compounds within a subgenus did not adequately describe such subgenus.

As outlined in Univ. of Cal. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), a description of a genus can comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under Section 112, Para. 1, by showing the

enablement of a representative number of species within the genus. Mere indistinct terms (here the words "phenyl-containing polymer", "nitric oxide releasing polymer", "means for" covalent linking), however, may not suffice to meet the written description requirement.

The instant specification does not describe specific "phenyl-containing polymers" other than PET and polystyrene. The listing of two species is far narrower in scope than the broad genus "phenyl-containing polymers" and claims 1, 2, 6, 7, 13, 18, 28 and 37 fail to recite any structural features common to the members of that genus which would constitute a substantial portion of the same. Accordingly, the term "phenyl-containing polymers" as used currently by instant claims 1, 2, 6, 7, 13, 18, 28 and 37 is deemed so indistinct that it fails to reasonably convey to one skilled in the art that applicant was in possession of a representative number of species within that genus.

The instant specification does not describe any specific "nitric oxide releasing polymers" and claims 49 and 51 fail to recite any structural features common to the members of that genus which would constitute a substantial portion of the same. Accordingly, the term "nitric oxide releasing polymers" as used currently by instant claims 49 and 51 is deemed so indistinct that it fails to reasonably convey to one skilled in the art that applicant was in possession of a representative number of species within that genus.

The instant specification only describes one specific "means for" covalently linking. The listing of one species is far narrower in scope than the broad genus "means for". Accordingly, the term "means for" as used currently in claim 37 is deemed so

indistinct that it fails to reasonably convey to one skilled in the art that applicant was in possession of a representative number of species within that genus.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6, 7, 13, 18, 28, 37, 49 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "R₁" is defined only in terms of what it is not, and therefore renders the claims indefinite.

Claim 3 recites the limitation "terminal oxygen" in line 9 of the claim. There is insufficient antecedent basis for this limitation in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

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USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 28 recites the broad recitation "polymer is selected from a group consisting of", and the claim also recites "including grafts and copolymerizations" which is the narrower statement of the range/limitation.

Furthermore, the term "including" is inconsistent with the limitation of "polymers consisting of" and renders the claim indefinite.

The term "carbon-based", as recited repeatedly throughout the claims, renders the claims indefinite. The examiner is not able to determine how closely related a compound must be to carbon to qualify as "based on carbon".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cafferata (U.S. Patent Publication 2003/0083739) in view of Arnold et al.(a) (Nitric Oxide, 2002).

Cafferata teaches a composition for controlled delivery of a systemic drug which provides nitrogen-based NO-releasing compounds at a localized site via a delivery stent (Abstract, paragraphs [0016], [0018]). The NO-releasing groups are bound as pendant groups attached to molecules and/or polymers covalently linked to a metal surface, i.e. a medical device, such as a metallic stent, which is used as a vascular stent (paragraphs [0020]-[0021], [0035] and [0042]). The composition is applied to the medical device by either spraying or immersing the device in the solution, i.e. a coating (paragraph 0035). The polymers suitable for the invention include polyvinyl aromatics, such as polystyrene (paragraph [0037]).

Cafferata does not teach a composition comprised of a carbon-based diazeniumdiolate compound attached to at least one phenyl containing polymer.

Arnold et al.(a) teaches that nitrogen bound diazeniumdiolates have the pitfall of forming N-nitrosamines which are carcinogenic. This complication can be avoided by attaching the diazeniumdiolate group to a carbon atom, i.e. a carbon-based diazeniumdiolate (page 2002, 1st column, 1st paragraph).

Arnold et al.(a) does not teach a composition comprising a NO-releasing compound which is carbon-based and attached to a phenyl containing polymer.

At the time of the invention, it would have been obvious to modify the composition of Cafferata to include the carbon-based diazeniumdiolate compound of Arnold et al.(a) motivated by the desire to produce a composition that does not have the pitfall of producing carcinogens as taught by Arnold et al.(a)

2) Claims 3, 4, 6, 7, 13, 18, 28, 37, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cafferata (U.S. Patent Publication 2003/0083739) in view of Arnold et al.(b) (Org. Letters, 2002) and further in view of Arnold et al.(a) (Nitric Oxide, 2002).

Cafferata is discussed above.

Cafferata does not teach that the NO-releasing compound is carbon-based; or that the compound is comprised of a cyano functionality or of a sodium counteraction.

Arnold et al.(b) teaches a carbon-based diazeniumdiolate that is of the formula of instant claim 3. The compound is NO-releasing at pH of 7.4 and is comprised of a sodium counterion (Title, Abstract, page 1324, 2nd column, Scheme 2). The use of the cyano group is an important tool for the introduction of diazeniumdiolate functional groups into organic compounds of potential medical interest (page 1325, 2nd column, 2nd paragraph).

Arnold et al.(b) does not teach a composition comprising a carbon-based

NO-releasing compound which is attached to a phenyl containing polymer or a medical device coated with such a compound.

Arnold et al.(a) is discussed above.

Arnold et al.(a) does not teach a composition comprising a carbon-based NO-releasing compound which is attached to a phenyl containing polymer or a medical device coated with such a compound.

At the time of the invention, it would have been obvious to modify the composition of Cafferata to include the carbon-based diazeniumdiolate compound of Arnold et al. motivated by the desire to produce a composition that does not have the pitfall of producing carcinogens as taught by Arnold et al (a). It would have also been obvious to include the cyano group to the compound of the composition since it is an important tool for the introduction of diazeniumdiolate functional groups into organic compounds of potential medical interest as taught by Arnold et al.(b).

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612